UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

MICHAEL TOBIN, INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED, ***Plaintiffs*****,**	§	
v.	§	**Cause No. 5:21-cv-921**
KONINKELIJKE PHILIPS, N.V.; PHILIPS NORTH AMERICA, LLC and PHILIPS RS NORTH AMERICA, ***Defendants*****.**	§	

PLAINTIFFS' ORIGINAL COMPLAINT

TO THE HONORABLE UNITED STATES DISTRICT COURT:

NOW COMES, Michael Tobin, Individually and on behalf of all other similarly situated individuals ("Plaintiffs"), and hereby file this Original Complaint, and in support thereof, respectfully show this Court as follows:

I.
JURISDICTION AND VENUE

1. This Court has subject matter jurisdiction over this class action pursuant to 28 U.S.C. § 1332, as amended by the Class Action Fairness Act of 2005, because the matter in controversy exceeds $5 million, exclusive of interest and costs, and is a class action in which Plaintiff and some members of the Class are citizens of states different than Defendants. *See* 28 U.S.C. § 1332(d)(2)(A).

2. Venue is proper in this District because a substantial part of the events or omissions giving rise to the claim occurred in this District.

II.
PARTIES

3. Plaintiff **Michael Tobin** is an individual and resident of Texas. He was diagnosed with sleep apnea and purchased a Philips Respironics DreamStation CPAP device on or around July 2019. This device was subsequently included in a recall by Philips on June 14, 2021. He would not have purchased this product if he had known it was defective, contained a carcinogenic byproduct and respiratory irritants, and would be subject to a recall for containing defective materials. After using the machine, Plaintiff began to suffer irritation and inflammation to his nasal passages and airways, skin and eyes, headaches, and asthma-like symptoms, including difficulty breathing. Because of the recall, Plaintiff has been forced to cease the use of the device, and he does not have a replacement machine readily available. Plaintiff demands a refund, replacement with a non-defective device, costs for ongoing medical monitoring, and all other appropriate damages for all the injuries he has suffered as a result of his defective device.

4. Defendant **Koninklijke Philips N.V. ("Royal Philips")** is a Dutch multinational company established under the laws of the Netherlands—headquartered in Amsterdam, Netherlands—and is the parent company of Philips North America LLC and Philips RS North America LLC.

5. Defendant **Philips North America LLC** is a Delaware company with its principal place of business in Cambridge, Massachusetts.

6. Defendant **Philips RS North America LLC ("Philips Respironics")**, formerly operated under the business name "Respironics," is a Delaware company headquartered in Pittsburgh, Pennsylvania, and manufacturers products for sleep and home respiratory care.

7. Reference to "Philips," "Defendant," or "Defendants" refers to each and every Defendant individually and collectively.

III.
FACTUAL BACKGROUND

8. Defendants manufacture and sell a variety of products that are intended to help people breathe, including Continuous Positive Airway Pressure ("**CPAP**") and Bilevel Positive Airway Pressure ("**BiPAP**") machines, which are commonly used to treat sleep apnea, and ventilators that treat respiratory failure. In general, each of the recalled devices express air into patients' airways. CPAP and BiPAP machines are intended for daily use, and ventilators are used continuously while needed. Without these devices, some patients may experience severe symptoms, including heart attack, stroke, and death by asphyxiation.

9. On April 26, 2021, Philips released its First-Quarter Results 2021 Report,[1] which stated the following vague notice regarding the company's "regulatory" updates:

Regulatory update

Philips has determined from user reports and testing that there are possible risks to users related to the sound abatement foam used in certain of Philips' sleep and respiratory care devices currently in use. The risks include that the foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone*), and certain environmental conditions involving high humidity and temperature. The majority of the affected devices are in the first-generation DreamStation product family. Philips' recently launched next-generation CPAP platform, DreamStation 2, is not affected. Philips is in the process of engaging with the relevant regulatory agencies regarding this matter and initiating appropriate actions to mitigate these possible risks. Given the estimated scope of the intended precautionary actions on the installed base, Philips has taken a provision of EUR 250 million.

[1] *See* https://www.philips.com/a-w/about/news/archive/corpcomms/news/press/2021/philips-first-quarter-results-2021.html (last visited September 15, 2021).

10. On June 14, 2021, Philips announced a voluntary recall[2] for millions of its Philips continuous positive airway pressure (CPAP), BiLevel positive airway pressure (BiLevel PAP) devices and mechanical ventilators (the "**Recalled Breathing Machines**").

11. The recall relates to the polyester-based polyurethane (PE-PUR) sound abatement foam used to dampen sound and vibration during routine operation, which may break down while devices are operating.

12. Philips specifically marketed its Recalled Breathing Machines to tout the "noise reducing enhancements," as "mitigating noise from the blower system." However, despite Defendants' misleading and misrepresentative advertising, the foam required to reduce the noise broke down the PE-PUR foam, which released particles and gases that are harmful if swallowed or inhaled. Specifically, Philips has determined from user reports and lab testing that the foam may degrade and produce particulates that can enter the device's air pathway and be inhaled by the user.

13. Chemical emissions from the PE-PUR foam, also called "off gassing," has been identified through Defendants' lab testing (performed for and by Philips) as being emitted from the foam and inhaled by users of the machines.

14. Volatile organic compounds (VOCs) used to manufacture the PE-PUR foam can be emitted from the foam, which emit two compounds of concern, as revealed in Philips' testing:

- Dimethyl diazine; and
- Phenol 2,6-his (1,1-dimethylethl)-4-(1-methylpropyl).

[2] *See* information regarding recall: https://www.usa.philips.com/healthcare/e/sleep/communications/src-update?gclid=Cj0KCQjwg7KJBhDyARIsAHrAXaHxWYvNsEj3MGMcr8mF3ODOz3TTnZZotf4vLGf4HG6LShPpLYaTl8oaAuKKEALw_wcB&gclsrc=aw.ds (last visited September 15, 2021); *see also* FDA recall information, available here: https://www.philips.com/a-w/about/news/archive/standard/news/press/2021/20210901-philips-starts-repair-and-replacement-program-of-first-generation-dreamstation-devices-in-the-us-in-relation-to-earlier-announced-recall-notification.html?src=search (last visited September 15, 2021).

15. These compounds can be carcinogenic and cause serious health issues, including cancer. Thus, the recall was classified by the FDA to be Class I, which is the most serious and means there is a reasonably probability that the user of, or exposure to, a violative product will cause serious adverse health consequences or death:

Q: What is the FDA's role in the Philips Respironics recall? (New 9/10/21)

A: The FDA has classified the Philips Respironics recall as a Class I recall, the most serious type of recall. Class I recalls present a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

The FDA reviewed and concurred with Philips' Respironics plan to rework the recalled DreamStation CPAP and BiPAP machines.

The FDA is committed to using every tool at our disposal to increase the availability of these medical products. The FDA is working with Philips Respironics to monitor the repair or replacement of impacted devices as expeditiously as possible and is continuing to gather information to inform our actions. We are collaborating with other manufacturers and government partners to support availability of CPAP and BiPAP machines.

In addition, the FDA has initiated on-site inspections of Philips Respironics' manufacturing facilities to assess compliance with regulatory requirements.

The FDA will continue to monitor the company's recall until Philips Respironics has met all requirements associated with a Class I recall and all recalled devices are repaired or replaced with safe and effective devices.

16. According to Phillips, the analysis of potential health risks is ongoing; however, Philips acknowledges that inhalation of the PE-PUR foam by CPAP machine users could cause serious, and even life-threatening damage, to the respiratory system. In an announcement entitled "Clinical information for physicians," Philips identifies the following health risks from PE-PUR foam inhalation or ingestion:

- Irritation and airway inflammation (particularly acute in patients with underlying lung or cardiopulmonary conditions);

- Headaches and dizziness;
- Chest pressure and sinus infection;
- Toxic and "carcinogenic effects"; and
- Damage to the kidney, liver, and other organs.

17. Philips was clearly aware of the problems with foam inhalation in its sleep apnea machines for a long time before it eventually issued its safety notice and recall in June 2021. Users of the recalled sleep apnea machines had been complaining for years about "black particles" in their lungs and similar issues. Despite being aware of these issues for years, Philips did not make a public safety announcement until April 2021 and the recall didn't come until June 2021. Philips appears to have deliberately delayed the timing of its recall to coincide with the release of its "next-generation" sleep apnea products that supposedly do not have the foam inhalation problem. Philips waited to tell consumers its existing products were dangerous until they had a new "safe" product to replace them.

18. On July 8, 2021, Sleep and Respiratory Care Update Clinical Information,[3] advising against use of a bacteria filter for the following devices:

[3] *See* https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/global-corporate/philips-global-bacteria-filter-document.pdf?_ga=2.8927925.1214138396.1631772165-400273868.1630348817&_gac=1.58645976.1630350030.Cj0KCQjwg7KJBhDyARIsAHrAXaHxWYvNsEj3MGMcr8mF3ODOz3TTnZZotf4vLGf4HG6LShPpLYaTl8oaAuKKEALw_wcB&_gl=1*1xulz49*_ga*NDAwMjczODY4LjE2MzAzNDg4MTc.*_ga_2NMXNNS6LE*MTYzMTc3MjE2NC4yLjEuMTYzMTc3NDgwMy4zOA (last visited September 15, 2021).

Affected CPAP/BiLevel Devices that are not recommended to be used with a Bacteria Filter

- SystemOne
- SystemOne ASV4
- DreamStation (CPAP, AutoCPAP, BiPAP)
- DreamStation GO (CPAP, AutoCPAP)
- DreamStation ASV
- DreamStation S/T, AVAPS
- Dorma 400, 500 CPAP
- REMStar SE Auto CPAP
- C Series (ASV, AVAPS, S/T)
- OmniLab Advanced Plus

(continued on next page)

19. On August 24, 2020, Sen. Richard Blumenthal (D-Conn.) sent a letter the CEO of Philips North America (Vitor Rocha), demanding information on how many patients are impacted by the recall, how many have been given repair kits and been contacted by Philips, and the company's "timeline for submitting a mitigation plan with sufficient evidence to [the Food and Drug Administration] for authorization of a permanent solution."[4]

20. On September 1, 2021, Philips received authorization from the FDA to begin repairing affected Recalled Breathing Machines.[5]

21. Additionally, on September 10, 2021, the FDA updated the frequently asked questions about Philips' recall.[6]

IV.
CLASS ALLEGATIONS

22. Plaintiff brings this action individually and as a class action pursuant to Fed. R. Civ. P. 23(a), 23(b)(2) and/or 23(b)(3). Specifically, the Classes that Plaintiff seeks to represent consist of the following:

> **Nationwide Class:** All persons in the United States who have purchased a Recalled Breathing Machine for personal use.

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[4] *See* letter, dated August 24, 2021, available here: https://www.blumenthal.senate.gov/imo/media/doc/2021.08.24_Letter%20to%20Philips%20re%20Device%20Recall.pdf (last visited September 15, 2021).

[5] *See* https://www.medtechdive.com/news/philips-recall-triggers-lawsuits-us-lawmaker-scrutiny/605682/ (last visited September 15, 2021).

[6] *See* https://www.fda.gov/medical-devices/safety-communications/philips-respironics-cpap-bipap-and-ventilator-recall-frequently-asked-questions (last visited September 15, 2021).

Texas Class: All persons in Texas who have purchased a Recalled Breathing Machine for personal use.

23. The Nationwide Class and the Texas Class are collectively referred to herein as the "Class." Excluded from the Class are Defendants and their employees, officers, and directors; and the Judge(s) and any mediator assigned to this case.

24. Plaintiff reserves the right to redefine the Class prior to class certification.

25. The rights of each member of the Class were violated in a similar fashion based upon Defendants' uniform actions.

26. This action has been brought and may be properly maintained as a class action for the following reasons:

27. Plaintiff brings this action individually and as a class action pursuant to Fed. R. Civ. P. 23(a), 23(b)(2) and/or 23(b)(3). Specifically, the Classes that Plaintiff seeks to represent consists of the following:

A. **Numerosity:** Members of the Class are so numerous that their individual joinder is impracticable. The proposed Nationwide Class contains at least millions of individuals, and the proposed Texas Class contains at least thousands of individuals, who purchased a Recalled Breathing Machine. The Class is therefore sufficiently numerous to make joinder impracticable, if not impossible. The precise number of Class members is unknown to Plaintiff at this time but the Class members are readily ascertainable and can be identified by Defendants' records.

B. **Existence and Predominance of Commons Questions of Fact and Law:** Common questions of law and fact exist as to all members of the Class. These questions predominate over any questions affecting only individual Class members. These common legal and factual questions include, without limitation:

   i. Whether Defendants were unjustly enriched by the sale of the Recalled Breathing Machines;

   ii. Whether Defendants were negligent in selling the Recalled Breathing Machines;

   iii. Whether Defendants failed to warn consumers regarding the risks of the Recalled Breathing Machines;

iv. Whether Defendants' practices constitute unfair or deceptive acts or practices under state consumer protection statutes;

v. The appropriate nature of class-wide equitable relief; and

vi. The appropriate measurement of restitution and/or measure of damages to Plaintiff and members of the Class.

These and other questions of law or fact that are common to the members of the Class predominate over any questions affecting only individual members of the Class.

C. **Typicality:** Plaintiff's claims are typical of the claims of all members of the Class who purchased the Recalled Breathing Machines for personal use.

D. **Adequacy:** Plaintiff is an adequate representative of the Class because his interests do not conflict with the interests of the Class that he seeks to represent; he has retained counsel competent and highly experienced in complex class action litigation, and they intend to prosecute this action vigorously. The interests of the Class will be fairly and adequately protected by Plaintiff and his counsel.

E. **Superiority:** A class action is superior to other available means of fair and efficient adjudication of the claims of Plaintiff and the Class. The injury suffered by each Class member is relatively small in comparison to the burden and expense of individual prosecution of the complex and extensive litigation necessitated by Defendants' conduct. It would be virtually impossible for members of the Class to individually and effectively redress the wrongs done to them. Even if the members of the Class could afford such individual litigation, the court system could not. Individualized litigation presents a potential for inconsistent or contradictory judgments. Individualized litigation also increases the delay and expense to all parties, and to the court system, presented by the complex legal and factual issues of the case. By contrast, the class action device presents far fewer management difficulties, and provides the benefits of single adjudication, an economy of scale, and comprehensive supervision by a single court.

V.
EQUITABLE TOLLING OF STATUTES OF LIMITATIONS

28. The running of any statute of limitations has been equitably tolled by reason of Defendants' fraudulent concealment and/or omissions of critical safety information. Through its affirmative misrepresentations and omissions, Philips actively concealed from Plaintiff and their physicians the true risks associated with the Recalled Breathing Machines.

29. As a result of Defendants' actions, Plaintiff and the Class members were unaware, and could not have reasonably known or learned through reasonable diligence, that they had been exposed to the risks and harms set forth and that those risks and harms were the direct and proximate result of Defendants' acts and omissions.

VI.
CAUSES OF ACTION

COUNT I
NEGLIGENCE

30. Plaintiff incorporates by reference all preceding paragraphs.

31. Defendants had a duty to Plaintiff and Class members, to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of its products, into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects.

32. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of its recalled products into interstate commerce in that Defendants knew or should have known that using its products could proximately cause Plaintiff's injuries. Specifically, Defendants failed to meet their duty to use reasonable care in the testing, creating, designing, manufacturing, labeling, packaging, marketing, selling, and warning of Defendants' products.

33. Defendants are liable for acts and/or omissions amounting to negligence, gross negligence and/or malice including, but not limited to the following:

A. Failure to adequately warn Plaintiff and Plaintiff's physicians of the known or reasonably foreseeable danger that Plaintiff would suffer a serious injury or death by using Defendants' products, namely the Recalled Breathing Machines;

B. Failure to use reasonable care in testing and inspecting Defendants' products (i.e., the Recalled Breathing Machines), so as to ascertain whether or not they were safe for the purpose for which they were designed, manufactured and sold;

C. Failure to use reasonable care in implementing and/or utilizing a reasonably safe design in the manufacture of Defendants' products;

D. Failure to use reasonable care in the process of manufacturing its products in a reasonably safe condition for the use for which it was intended; and

E. Failure to use reasonable care in the manner and method of warning Plaintiff and Plaintiff's physicians as to the danger and risks of using its products.

34. Such further acts and/or omissions that may be proven at trial.

35. The above-described acts and/or omissions of Defendants were a direct and proximate cause of the severe, permanent and disabling injuries and resulting damages to Plaintiff and the Class.

36. Plaintiff and the Class suffered damages in an amount to be determined at trial.

COUNT II
STRICT LIABILITY-FAILURE TO WARN

37. Plaintiff incorporates by reference all preceding paragraphs.

38. Defendants had a duty to warn Plaintiff and the Class members regarding the defect and true risks associated with the Recalled Breathing Machines.

39. Defendants failed to provide adequate warnings regarding the risks of the PE-PUR foam.

40. Defendants had information regarding the true risks but failed to warn Plaintiff, Class members, and their physicians to strengthen their warnings.

41. Despite Defendants' obligation to unilaterally strengthen the warnings, Philips instead chose to actively conceal this knowledge.

42. Plaintiff and Class members would not have purchased, chosen, and/or paid for all or part of the Recalled Breathing Machines if they knew of the defect and the risks of purchasing the product.

43. This defect proximately caused Plaintiff's and Class members' injuries which include economic injuries, as well as headache, irritation, inflammation, respiratory issues, and exposure to materials with toxic and carcinogenic effects.

44. Plaintiff and the Class suffered damages in an amount to be determined at trial.

COUNT III
STRICT LIABILITY – DESIGN DEFECT

45. Plaintiff incorporates by reference all preceding paragraphs.

46. The design of the Recalled Breathing Machines, including, but not limited to, design and use of the PE-PUR foam and the placement of the foam within the Recalled Breathing Machines, was defective and unreasonably dangerous, causing degradation and inhalation of the PE-PUR foam, and causing headaches, irritation, inflammation, respiratory issues, and exposure to materials with toxic and carcinogenic effects.

47. The design of the Recalled Breathing Machines and the PE-PUR foam rendered the Recalled Breathing Machines not reasonably fit, suitable, or safe for their intended purpose.

48. The dangers of the Recalled Breathing Machines outweighed the benefits and rendered the products unreasonably dangerous. Indeed, there are other CPAP and other machines that do not use a similarly toxic foam that is subject to degradation, inhalation, and ingestions.

49. Safer, alternative machines from other manufacturers were available that did not suffer from the defect as set forth herein and that did not have an unreasonable risk of harm as with the Recalled Breathing Machines and their unsafe PE-PUR foam.

50. The risk benefit profile of the Recalled Breathing Machines was unreasonable, and the products should have had stronger and clearer warnings or should not have been sold in the market.

51. The Recalled Breathing Machines did not perform as an ordinary consumer would expect.

52. Plaintiff and the Class suffered damages in an amount to be determined at trial.

COUNT IV
STRICT LIABILITY – MANUFACTURING DEFECT

53. Plaintiff incorporates by reference all preceding paragraphs.

54. The Recalled Breathing Machines were originally designed, manufactured, and sold by Defendant Philips. At the time the Trailer in question was sold, Defendant was in the business of designing, manufacturing, selling, and/or otherwise placing CPAP machines, such as the Recalled Breathing Machines in question, in the stream of commerce.

55. The Recalled Breathing Machine reached Plaintiff and Class Members in the condition expected and intended by Defendant.

56. Plaintiff used the Affected CPAP/BiLevel PAP device for its intended and foreseeable purpose.

57. When it left control of Defendants, defects in the manufacture of the Recalled Breathing Machines rendered them defective and unreasonably dangerous in that the polyester-based polyurethane (PE-PUR) sound abatement foam used to dampen sound and vibration during routine operation, contained dangerous chemicals which lead to severe medical conditions, and even death.

58. The defective manufacture of the Recalled Breathing Machines directly and proximately caused Plaintiff's damages and the damages of the Class Members.

59. Plaintiff and the Class suffered damages in an amount to be determined at trial.

COUNT V
NEGLIGENT FAILURE TO WARN

60. Plaintiff and the Class incorporate by reference all preceding paragraphs.

61. Defendants owed Plaintiff and Class members a duty of care and to warn of any risks associated with the Recalled Breathing Machines. Defendants knew or should have known of the true risks but failed to warn Plaintiff, Class members, and their doctors.

62. Defendants' negligent breach of duty caused Plaintiff and Class members economic damages and injuries in the form of headaches, irritation, inflammation, respiratory issues, and exposure to materials with toxic and carcinogenic effects.

63. Plaintiff and Class members would not have purchased, chosen, and/or paid for all or part of the Recalled Breathing Machines if they knew of the defect and the risks associated with purchasing the product.

64. Plaintiff and the Class suffered damages in an amount to be determined at trial.

COUNT VI
NEGLIGENT DESIGN DEFECT

65. Plaintiff and the Class incorporate by reference all preceding paragraphs.

66. Defendants negligently designed the Recalled Breathing Machines. Philips owed Plaintiff and the Class a duty to design the Recalled Breathing Machines in a reasonable manner. The design of the Recalled Breathing Machines, including but not limited to the design of the PE-PUR foam and the placement of the PE-PUR foam within the Recalled Breathing Machines, was defective and unreasonably dangerous, causing degradation and inhalation of the foam, and causing headaches, irritation, inflammation, respiratory issues, and exposure to materials with toxic and carcinogenic effects.

67. The design of the Recalled Breathing Machines and the PE-PUR foam rendered the Recalled Breathing Machines not reasonably fit, suitable, or safe for their intended purpose.

68. The dangers of the Recalled Breathing Machines outweighed the benefits and rendered the products unreasonably dangerous. Indeed, there are CPAP and other machines that do not use a similarly toxic foam that is subject to degradation, inhalation, and ingestions.

69. Safer, alternative machines from other manufacturers were available that did not have an unreasonable risk of harm as with the Recalled Breathing Machines and their unsafe foam.

70. The risk benefit profile of the Recalled Breathing Machines was unreasonable, and the products should have had stronger and clearer warnings or should not have been sold in the market.

71. The Recalled Breathing Machines did not perform as an ordinary consumer would expect.

72. Plaintiff and the Class suffered damages in an amount to be determined at trial.

COUNT VII
NEGLIGENT RECALL

73. Plaintiff and the Class incorporate by reference all preceding paragraphs.

74. In issuing a voluntary recall, Philips assumed duties to Plaintiff and the Class to exercise reasonable care in issuing and implementing the recall.

75. Philips breached its duties by failing to adequately warn Plaintiff and the Class of the dangers associated with the use of the Recalled Breathing Machines by refusing to promptly repair or replace the Recalled Breathing Machines.

76. As a direct result of Defendants' breach of duty, Plaintiff and the Class have suffered harm in an amount to be determined at trial.

COUNT VIII
BREACH OF EXPRESS WARRANTY

77. Plaintiff and the Class incorporate by reference all preceding paragraphs.

78. Defendants warranted the Recalled Breathing Machines "shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of two (2) years from the date of sale."

79. Defendants breached this express warranty in connection with the sale and distribution of the Recalled Breathing Machines. At the point of sale, the Recalled Breathing Machines while appearing normal—contained immediate defects as set forth herein, rendering them unsuitable and unsafe for personal use by humans.

80. Had Plaintiff and the Class known the Recalled Breathing Machines were unsafe for use, they would not have purchased them.

81. Defendants have breached their warranty and refused to provide appropriate warranty relief notwithstanding the risks of using the Recalled Breathing Machines. Plaintiff and the Class reasonably expected, at the time of purchase, that the Recalled Breathing Machines were safe for their ordinary and intended use.

82. Defendants breached the aforementioned express warranties, as their Recalled Breathing Machines were defective.

83. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that Defendants' products, including the Recalled Breathing Machines, were not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.

84. As a result of the foregoing acts and omissions, Plaintiff and the Class was caused to suffer serious and dangerous side effects, which are permanent and/or long-lasting in nature.

85. As a result of the foregoing, Plaintiff and the Class will require more health care services and did incur medical, health, incidental and related expenses, and believe same will be required in the future, for further medical and/or hospital care, attention, and services.

86. As a direct and proximate result of Defendants' breach of express warranty, Plaintiff and the Class have sustained damages in an amount to be determined at trial.

COUNT IX
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

87. Plaintiff and the Class incorporate by reference all preceding paragraphs.

88. By operation of law, Defendants, as manufacturers of the Recalled Breathing Machines and as the providers of a limited warranty for the Recalled Breathing Machines, impliedly warranted to Plaintiff and the Class that the Recalled Breathing Machines were of merchantable quality and safe for their ordinary and intended use.

89. Defendants breached the implied warranty of merchantability in connection with the sale and distribution of the Recalled Breathing Machines. At the point of sale, the Recalled Breathing Machines while appearing normal—contained defects as set forth herein rendering them unsuitable and unsafe for personal use by humans.

90. Had Plaintiff and the Class known the Recalled Breathing Machines were unsafe for use, they would not have purchased them.

91. Defendants have refused to provide appropriate warranty relief notwithstanding the risks of using the Recalled Breathing Machines. Plaintiff and the Class reasonably expected, at the time of purchase, that the Recalled Breathing Machines were safe for their ordinary and intended use.

92. As a direct and proximate result of Defendants' breach of the implied warranty of merchantability, Plaintiff and the Class have sustained damages in an amount to be determined at trial.

COUNT X
TEXAS DECEPTIVE TRADE PRACTICES ACT
(Tex. Bus. Code § 17.46)
On Behalf of the Texas Class

93. Plaintiff incorporates by reference all preceding paragraphs.

94. Pursuant to Tex. Bus. Code § 17.46, "[f]alse, misleading, or deceptive acts and practices in the conduct of any trade or commerce are hereby declared unlawful and area subject to action by the consumer protection division[.]"

95. Plaintiff and Class members are considered "consumers" under Tex. Bus. Code § 17.45(4), in that they are individuals who sought or acquired, by purchase or by lease, a good or service (i.e., Defendants' Recalled Breathing Machines). Accordingly, Plaintiff and Class members are entitled to bring the instant cause of action for damages in accordance with Tex. Bus. Code § 17.50.

96. Defendants engaged in unfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce, with respect to the sale and advertisement of the Recalled Breathing Machines purchased by Plaintiff and Texas Class Members, in violation of Tex. Bus. Code § 17.46, *et seq*., including by misrepresenting the true quality of the Recalled Breathing Machines, and concealing the true risks of the Recalled Breathing Machines. *See also* Tex. Bus. Code § 17.45(5) (defining "unconscionable action or course of action" to mean "an act or practice which, to a consumer's detriment, takes advantage of the lack of knowledge, ability, experience, or capacity of the consumer to a grossly unfair degree.").

97. The above unfair methods of competition and unfair or deceptive acts or practices by Defendants were conducted in "[t]rade" and/or "commerce," as defined by Tex. Bus. Code § 17.45.

98. The above unfair methods of competition and unfair or deceptive acts or practices by Defendants were immoral, unethical, oppressive, and unscrupulous.

99. Defendants' actions were negligent, knowing, and willful, and/or wanton and reckless with respect to the rights of Plaintiff and the Texas Class members.

100. Plaintiff and Texas Class members relied on Defendants' representations in that they would not have purchased, chosen, and/or paid for all or part of the Recalled Breathing Machines had they known the true risks of the products.

101. As a direct and proximate result of Defendants' deceptive trade practices and acts, Plaintiff and Texas Class Members suffered an ascertainable loss of money or property, real or personal, as described above.

102. Plaintiffs and Texas Class members seek relief under Tex. Bus. Code § 17.45, *et seq*., including, but not limited to injunctive relief, statutory damages, economic damages, mental anguish, punitive damages, civil penalties and attorneys' fees and costs.

COUNT XI
UNJUST ENRICHMENT
(In the Alternative)

103. Plaintiff and the Class incorporate by reference all preceding paragraphs.

104. Plaintiff and the Class members conferred a tangible and material economic benefit upon Defendants by purchasing the Recalled Breathing Machines. Plaintiff and Class members would not have purchased, chosen and/or paid for all or part of Recalled Breathing Machines had they known the true risks of using the Recalled Breathing Machines. Defendants are not providing a timely repair or replacement for the Recalled Breathing Machines. Under these circumstances,

it would be unjust and inequitable for Defendants to retain the economic benefits they received at the expense of Plaintiff and the Class.

105. Failing to require Defendants to provide remuneration under these circumstances would result in Defendants being unjustly enriched at the expense of Plaintiff and the Class members who endure being exposed to the risk of developing serious medical conditions and can no longer use their Recalled Breathing Machines safely.

106. Defendants' retention of the benefit conferred upon them by Plaintiff and the Class would be unjust and inequitable.

107. Plaintiff and the Class suffered damages in an amount to be determined at trial.

VII.
PRAYER FOR RELIEF

108. **WHEREFORE**, Plaintiff requests, individually and on behalf of all other similarly situated members of the Class, that this Court:

A. Determine that the claims alleged herein may be maintained as a class action under Rule 23(a), (b)(2), and/or (b)(3) of the Federal Rules of Civil Procedure on behalf of the Nationwide Class and Texas Class defined above, and designate Plaintiff as the class representative, and Plaintiff's counsel as Class Counsel;

B. Award equitable and injunctive relief, including but not limited to, requiring Defendants to institute a medical monitoring program for Plaintiff and Class members, restitution, and disgorgement of profits;

C. Award all actual, general, special, incidental, punitive, and consequential damages to which Plaintiff and Class members are entitled;

D. Award pre-judgment and post-judgment interest on such monetary relief;

E. Award reasonable attorneys' fees and costs; and

F. Grant such further and other relief that this Court deems appropriate.

VIII.
JURY DEMAND

109. Plaintiff and the Class demand a trial by jury on all issues so triable.

Date: September 27, 2021

Respectfully Submitted,

By: */s/ Robert C. Hilliard*
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